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M. Bud Nelson

Name

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16 Sept 2003

Date of Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Jie Di, David Heilman, Brian Bray

Application No.

Examiner:

Filed: 16 September 2003

Art Unit

For: Pharmaceutical composition for improved administration of HIV gp41-derived peptides, and its use in therapy

Commissioner for Patents  
Alexandria, VA

**Docket No. TRM-003**

**INFORMATION DISCLOSURE STATEMENT**

**37 CFR 1.56 and 1.97**

Applicants wish to make of record the following references under the provisions of 37 CFR 1.56 and 1.97 **and** to provide a copy of relevant background with respect to the application. The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application, or is to be considered material to patentability as defined in 37 CFR §1.56(b).  
Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove any document as a cited reference against the claims of the present invention.

**References Cited**

Please see attached Form PTO-1449 for list of publications, legible copies of all publication listed are enclosed.

**Statement of Relevancy**

Cites 2, 3, 5, and 6 generally relate to HIV gp41-derived peptides, and formulations thereof.

Cites 1, 4, 7, and 8 generally relate to polyols (e.g. PEG) use with proteins.

Respectfully submitted,

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Attorney for the Applicants

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>				Docket Number (Optional) <b>TRM-003</b>		Application Number	
				Applicant(s) <b>Jie Di, David Heilman, Brian Bray</b>		Filing Date <b>16 September 2003</b>	
<b>U.S. PATENT DOCUMENTS</b>							
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	5,462,863	10/31/1995	Hsieh et al.			
	2	5,464,933	11/07/1995	Bolognesi et al.			
	3	5,656,480	08/12/1997	Wild et al.			
	4	6,004,549	12/21/1999	Reichert et al.			
	5	6,573,078	06/03/2003	Wild et al.			
	6	6,348,568	02/19/2002	Barney et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
<b>OTHER DOCUMENTS</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	7	Middaugh et al., "Protein Solubility", Chapter 4 in "Stability of Protein Pharmaceuticals", edited by Ahern and Manning. Plenum Press, 1992, pages 109-113.					
	8	Middaugh et al., "Determination of the apparent thermodynamic activities of saturated protein solutions", 1979, pp. 367-370, Vol. 254, No. 3. The Journal of Biological Chemistry.					
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			
<b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							